IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS

JOHN MARK DEVOUS, Plaintiff, vs. *MEDTRONIC USA, INC., MEDTRONIC, INC., MEDTRONIC MINIMED, INC., and MINIMED DISTRIBUTION, INC.,* Defendants.	)	Civil No.: 3:19-cv-00201-JPG-RJD **JURY TRIAL DEMANDED**

DEFENDANT MEDTRONIC, INC.'S
ANSWER TO PLAINTIFF'S COMPLAINT

COMES NOW Defendant Medtronic, Inc. ("Medtronic" or "Defendant"), by and through its undersigned counsel, for its Answer to Plaintiff's Complaint hereby states as follows:

JURISDICTION

1. Medtronic lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 1 of the Complaint, and therefore denies same.

2. Medtronic admits that Medtronic, Inc., is a corporation organized under the laws of the State of Minnesota with its principal place of business at 710 Medtronic Parkway, Minneapolis, Minnesota 55432.

3. Medtronic admits that Medtronic USA, Inc., is a corporation organized under the laws of the State of Minnesota with its principal place of business at 710 Medtronic Parkway, Minneapolis, Minnesota 55432.

4. Medtronic admits that Medtronic MiniMed, Inc., is a corporation organized under the laws of the State of Delaware with its principal place of business located at 18000 Devonshire Street, Northridge, California 91325.

5. Medtronic admits that MiniMed Distribution, Corp., is a corporation organized under the laws of the State of Delaware with its principal place of business located at 18000 Devonshire Street, Northridge, California 91325. Medtronic denies the remaining allegations set forth in Paragraph 5.

6. Paragraph 6 of the Complaint states a legal conclusion to which no response is required. To the extent any of the allegations in Paragraph 6 can be deemed factual and interpreted to apply to Defendant, then it denies same.

7. Paragraph 7 of the Complaint states a legal conclusion to which no response is required. To the extent any of the allegations in Paragraph 7 can be deemed factual and interpreted to apply to Defendant, then it denies same.

FACTS

1. Medtronic denies that Plaintiff was injured as a result of a "defective Medtronics [sic] product." Medtronic is without sufficient knowledge or information to admit or deny the remaining allegations in Paragraph 1 of the Complaint,[1] and therefore denies same.

2. Medtronic admits that Plaintiff was prescribed a Medtronic MiniMed 630G insulin pump. Medtronic lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 2 of the Complaint, and therefore denies the same.

[1] Plaintiff's Complaint restarts its paragraph numbering in the Facts section.

3. Medtronic generally admits that the Medtronic MiniMed 630G insulin pump is used in conjunction with Medtronic MiniMed infusion sets to deliver insulin to insulin pump users. Medtronic denies the remaining allegations set forth in Paragraph 3.

4. Medtronic denies that Defendant Medtronic, Inc., is or was responsible for the design, manufacture, marketing or distribution of Plaintiff's Medtronic MiniMed 630G insulin pump or MiniMed Quick-set infusion sets. The remaining allegations contained in Paragraph 4 are not directed to this Defendant and, as such, requires no response. To the extent any of the remaining allegations can be deemed factual and interpreted to apply to this Defendant, then Defendant denies same.

5. Medtronic generally admits that insulin is delivered from the insulin reservoir in the Medtronic MiniMed 630G insulin pump to the patient's body through an infusion set. Medtronic denies the remaining allegations set forth in Paragraph 5.

6. Medtronic denies the allegations set forth in Paragraph 6.

7. Medtronic admits that prior to August 30, 2017, Plaintiff was prescribed a 630G insulin pump and MMT-396 Infusion Sets. Medtronic denies that Plaintiff's devices were defective in any way. Medtronic lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 7 of the Complaint, and therefore denies the same.

8. Medtronic denies that Plaintiff's devices were defective in any way. Medtronic lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 8 of the Complaint, and therefore denies the same.

9. Medtronic denies that Plaintiff's devices were defective in any way. Medtronic lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 9 of the Complaint, and therefore denies the same.

10. Medtronic lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 10 of the Complaint, and therefore denies the same.

11. Medtronic lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 11 of the Complaint, and therefore denies the same.

12. Medtronic lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 12 of the Complaint, and therefore denies the same.

13. Medtronic denies the allegations set forth in Paragraph 13.

14. Medtronic denies that Plaintiff's devices were defective in any way. Medtronic lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 14 of the Complaint, and therefore denies the same.

15. Medtronic admits that on September 7, 2017, Medtronic MiniMed, Inc., initiated a voluntary recall of certain Medtronic MiniMed Infusion Sets. Medtronic denies the remaining allegations set forth in Paragraph 15.

16. Medtronic admits that on September 7, 2017, Medtronic MiniMed, Inc., initiated a voluntary recall of certain Medtronic MiniMed Infusion Sets. Medtronic specifically denies that any infusion set allegedly used by Plaintiff was defective in any way. Medtronic denies the remaining allegations set forth in Paragraph 16.

17. Medtronic admits that on September 7, 2017, Medtronic MiniMed, Inc., initiated a voluntary recall of certain Medtronic MiniMed Infusion Sets. The document is a writing that

speaks for itself. Medtronic further states that Plaintiff's quotations are incomplete, taken out of context and misleading. Medtronic denies the remaining allegations set forth in Paragraph 17.

18. Medtronic admits that on September 7, 2017, Medtronic MiniMed, Inc., initiated a voluntary recall of certain Medtronic MiniMed Infusion Sets. The document is a writing that speaks for itself. Medtronic denies the remaining allegations set forth in Paragraph 18.

19. Medtronic admits that on September 7, 2017, Medtronic MiniMed, Inc., initiated a voluntary recall of certain Medtronic MiniMed Infusion Sets. The document is a writing that speaks for itself. Medtronic further states that Plaintiff's quotations are inaccurate and/or incomplete. Medtronic denies the remaining allegations set forth in Paragraph 19.

20. Medtronic denies the allegations in Paragraph 20 of the Complaint as phrased.

21. Medtronic denies the allegations set forth in Paragraph 21.

COUNT I

22. Medtronic denies that Defendant Medtronic, Inc., is or was responsible for the design, manufacture, marketing, testing, labeling, selling or distribution of Plaintiff's MiniMed Quick-set infusion sets. The remaining allegations contained in Paragraph 22 are not directed to this Defendant and, as such, requires no response. To the extent any of the remaining allegations can be deemed factual and interpreted to apply to this Defendant, then Defendant denies same.

23. Medtronic denies the allegations set forth in Paragraph 23.

24. Medtronic denies the allegations set forth in Paragraph 24.

25. Medtronic denies the allegations set forth in Paragraph 25.

26. Medtronic denies the allegations set forth in Paragraph 26.

WHEREFORE, having fully answered the allegations contained in Count I of Plaintiff's Complaint, Medtronic respectfully requests judgement in its favor, an Order dismissing same,

awarding Medtronic, Inc., its costs incurred herein, and for such other and further relief as the Court deems just and proper in the premises.

COUNT II

Negligence and Willful and Wanton Misconduct

27. Medtronic denies the allegations set forth in Paragraph 27.

28. Medtronic denies the allegations set forth in Paragraph 28.

29. Medtronic denies the allegations set forth in Paragraph 29, and each and every sub-paragraph contained therein.

30. Medtronic denies the allegations set forth in Paragraph 30.

WHEREFORE, having fully answered the allegations contained in Count II of Plaintiff's Complaint, Medtronic respectfully requests judgement in its favor, an Order dismissing same, awarding Medtronic, Inc., its costs incurred herein, and for such other and further relief as the Court deems just and proper in the premises.

AFFIRMATIVE DEFENSES

COMES NOW, Medtronic, by and through its attorneys, and hereby pleads the following separate and independent affirmative defenses to Plaintiff's Complaint:

FIRST AFFIRMATIVE DEFENSE
PLAINTIFF'S CONTRIBUTORY FAULT AND NEGLIGENCE

Plaintiff's injuries and damages were caused by Plaintiff John DeVous' own contributory fault and negligence in that he failed to use that degree of skill and care that an ordinarily careful and prudent person would use under the same or similar circumstances. Plaintiff's contributory fault and negligence includes engaging in activities that caused or contributed to cause the alleged malfunction and or injuries described in the Complaint. Consequently, Plaintiff's claims are barred in the event Plaintiff's contributory fault and negligence was more than 50% of the proximate

cause of the injury or damage for which recovery is sought or, in the alternative, if Plaintiff's contributory negligence and fault was 50% or less of the proximate cause of the injury or damage for which recovery is sought, then Medtronic is entitled to a reduction of damages based upon Plaintiff's percentage of fault or negligence.

SECOND AFFIRMATIVE DEFENSE
ASSUMPTION OF RISK/INFORMED CONSENT

Plaintiff's claims are barred in whole or in part by the assumption of the risk doctrine in that Plaintiff was fully aware of and informed of the nature of the medical device's risks and Plaintiff accepted and assumed all risks. For example, Plaintiff was aware that use of medical devices carries risks of additional injury and complication and relied on the judgment and expertise of his physician.

THIRD AFFIRMATIVE DEFENSE
FAILURE TO MITIGATE DAMAGES

Plaintiff's claims are barred in whole or in part to the extent Plaintiff failed to exercise reasonable care and diligence to mitigate his injuries and/or damages.

FOURTH AFFIRMATIVE DEFENSE
MODIFICATION OR ALTERATION

Plaintiff's claims are barred in whole or in part to the extent Plaintiff's conduct or a third party's conduct changed, altered, or modified the condition of the devices and/or products at issue and such change, alteration, or modification caused or contributed to cause Plaintiff's alleged injuries or damages.

FIFTH AFFIRMATIVE DEFENSE
PRODUCT MISUSE

Plaintiff's claims are barred in whole or in part to the extent Plaintiff or others misused the devices and/or products at issue.

SIXTH AFFIRMATIVE DEFENSE
PRODUCT MISUSE CONTRARY TO EXPRESS INSTRUCTIONS/WARNINGS

Plaintiff's claims are barred in whole or in part to the extent that Plaintiff used the devices and/or products at issue in a manner or in an activity contrary to express adequate instructions or warnings appearing on or attached to the product or on the product's original containers and/or wrappers, operator's manuals, or other documents provided with the devices and/or products.

SEVENTH AFFIRMATIVE DEFENSE
CONTRIBUTORY OR COMPARATIVE NEGLIGENCE/INTERVENING OR SUPERSEDING CAUSE

While denying all averments of negligence, fault, or liability, Medtronic states that Plaintiff's alleged injuries or damages were caused, in whole or in part, solely from the acts or omissions of persons or entities for which Medtronic is neither liable nor responsible, and/or from intervening or superseding events, factors, occurrences, or conditions for which Medtronic is not liable. Such acts or omissions on the part of others, and/or such intervening or superseding events, factors, occurrences, or conditions, constitute an independent and intervening and/or superseding proximate cause of such injuries or damages. The contributory or comparative fault of Plaintiff and/or other persons outside Medtronic's control is a complete bar to any recovery against it. Alternatively, Medtronic is entitled to a reduction of damages based upon Plaintiff's and/or other persons' percentage of negligence or fault.

EIGHTH AFFIRMATIVE DEFENSE
RESTATEMENT (SECOND) OF TORTS § 402A

Plaintiff's claims are barred, in whole or in part, under Comment K of Section 402A of the RESTATEMENT (SECOND) OF TORTS, which provides that unavoidably unsafe products, properly prepared and accompanied by proper directions and warnings, are neither defective nor

unreasonably dangerous. *See also* RESTATEMENT (THIRD) OF TORTS: PRODUCT LIABILITY §§§ 2, 4, 6.

NINTH AFFIRMATIVE DEFENSE
FEDERAL PREEMPTION

Plaintiff's claims are preempted by federal law, including but not limited to the Medical Device Amendments Act of 1976, 21 U.S.C. § 360(c), et seq.; the Federal Food, Drug & Cosmetic Act, 21 U.S.C. § 301, et seq.; and the regulations promulgated pursuant to those Acts. Specifically, Plaintiff's insulin pump is a Class III medical device approved by the Food and Drug Administration ("FDA") pursuant to its premarket approval process. As such, Plaintiff's claims are or may be, as a matter of law, preempted, in whole or in part, by federal law, specifically 21 U.S.C. § 360k(a), as stated in the United States Supreme Court's decision in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008).

TENTH AFFIRMATIVE DEFENSE
STATE OF THE ART

Plaintiff's claims are barred, in whole or in part, because the devices and/or products described in the Complaint, at all times relevant hereto, complied with all applicable laws and regulations, as well as all applicable industry and FDA standards, regulations, and guidance, industry custom, and available technological, scientific, and industrial state of the art at the time they were designed, manufactured, tested, marketed, and labeled. As such, Plaintiff's claims are barred by the state of the art defense.

ELEVENTH AFFIRMATIVE DEFENSE
SETOFF

Medtronic is entitled to a setoff or reduction of the claim against it by the greater of the stipulated amount of any release, covenant not to sue, or covenant not to enforce judgment or by

the amount of consideration paid for the release, covenant not to sue, or not to enforce judgment pursuant to 740 ILCS § 100/2 should the contingencies contemplated by that section occur.

TWELFTH AFFIRMATIVE DEFENSE
NO PRIVATE CAUSE OF ACTION

Plaintiff's claims are barred in whole or in part because there is no private right of action under the Federal Food, Drug & Cosmetic Act or the Medical Device Amendments thereto. *See* 21 U.S.C. § 337(a). Therefore, to the extent Plaintiffs' claims rest upon alleged violations of federal regulations, the claims are impliedly preempted as set forth in *Buckman Co. v. Plaintiffs' Legal Committee,* 531 U.S. 341 (2001).

THIRTEENTH AFFIRMATIVE DEFENSE
LEARNED INTERMEDIARY

Plaintiff's claims are barred in whole or part by the learned intermediary doctrine.

FOURTEENTH AFFIRMATIVE DEFENSE
FAILURE TO STATE A CLAIM UPON WHICH RELIEF CAN BE GRANTED

Plaintiff's Complaint and each and every purported cause of action therein fails to state a claim upon which relief can be granted, and the Complaint should therefore be dismissed in its entirety.

FIFTEENTH AFFIRMATIVE DEFENSE
IMPROPERLY NAMED DEFENDANTS

Plaintiff's claims against Medtronic, Inc., and Medtronic USA, Inc., are barred because they are not proper parties to this action involving devices and/or products designed, manufactured, marketed, distributed, tested and sold by other Defendants and/or third parties.

SIXTEENTH AFFIRMATIVE DEFENSE
CLAIM FOR PUNITIVE DAMAGES UNCONSTITUTIONAL

Plaintiff's claim for punitive damages cannot be sustained because an award of punitive damages under the laws of the State of Illinois would violate this Defendant's procedural and substantive due process rights and equal protection rights under the Sixth Amendment to the United States Constitution, and would be contrary to the Fourteenth Amendment to the United States Constitution and this Defendant's rights under the Illinois Constitution. In particular, any law purporting to permit the recovery of punitive damages in this case is unconstitutional, both on its face and as applied in this case, in that said law, *inter alia*: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and in determining the amount of any punitive award; (2) unconstitutionally may permit jury consideration of Defendant's net worth; (3) is void for vagueness in that it failed to afford constitutionally sufficient advance notice as to what conduct will result in punitive sanctions; (4) lacks constitutionally sufficient standards to be applied by the trial court in post verdict review of a punitive reward; (5) lacks constitutionally sufficient standards for appellate review of a punitive award; and (6) otherwise fails to satisfy the constitutional requirements set forth in *State Farm v. Campbell*, 123 S.Ct. 1513 (2003), *Cooper Industries, Inc. v. Leatherman Tools Group*, 532 U.S. 424 (2001), *BMW of North America, Inc. v. Gore*, 116 S. Ct. 1589 (1996), *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443, 113 S. Ct. 271 1 (1993), and, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1, 11 1 S. Ct. 1032 (1991).

Plaintiff's claim for exemplary or punitive damages violates the Due Process Clause of the Fourteenth amendment to the United States Constitution and corresponding protections provided under the Illinois Constitution. Defendant did not participate, engage, or assist in any act or

conduct which could form a basis for an award of punitive damages and any award therefore is not recoverable to any extent whatsoever.

Further, Defendant states Plaintiff's claim for punitive damages cannot be sustained because the evidence fails to demonstrate willful and wanton conduct on behalf of Defendant entitling Plaintiff to punitive damages. Further, any award for punitive damages, without trying all punitive damage issues only if, and after, liability on the merits has been found, would violate Defendant's due-process rights guaranteed by the Fourteenth Amendment to the United States Constitution and would be improper under the Constitution and Public Policies of the State of Illinois.

Further, Plaintiff's claims for punitive damages is unconstitutional to the extent that Plaintiff's Complaint seeks to punish Defendant without the protection of constitutional safeguards including, but not limited to, proof beyond a reasonable doubt, the right to a speedy trial, the prohibitions against doubt jeopardy and excessive fines, the freedom from self-incrimination during the discovery process, and trial which is guaranteed under the Fifth, Sixth, Eighth, and Fourteenth Amendments to the Constitution of the United States and through the applicable provisions of the Constitution of the State of Illinois, and that any law of the State of Illinois, whether enacted by the Illinois legislature or founded upon decisions of Illinois courts, permitting Plaintiffs to recover punitive damages without protection of such safeguards is unconstitutional.

RIGHT TO ALLEGE FURTHER DEFENSES AS SUPPORTED BY EVIDENCE

Defendant reserves the right to assert all other affirmative defenses that become known to it through the course of discovery in this matter by seeking leave to amend or by consent of the parties as permitted by the rules.

WHEREFORE, having fully answered and defended, Medtronic prays for judgment as

follows:

A. That Plaintiff take nothing by his Complaint;

B. That the Court dismiss the Complaint with prejudice in its entirety;

C. That Medtronic be awarded the attorneys' fee and costs incurred in connection with this action; and

D. For such other and further relief as the Court deems just and proper.

Respectfully submitted,

STANTON | BARTON LLC

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ATTORNEYS FOR DEFENDANT MEDTRONIC, INC.

CERTIFICATE OF SERVICE

The undersigned certifies that a copy of the foregoing was sent this 3rd day of June 2019 to the following counsel via the Court's CM/ECF system:

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/s/ Jonathan T. Barton
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